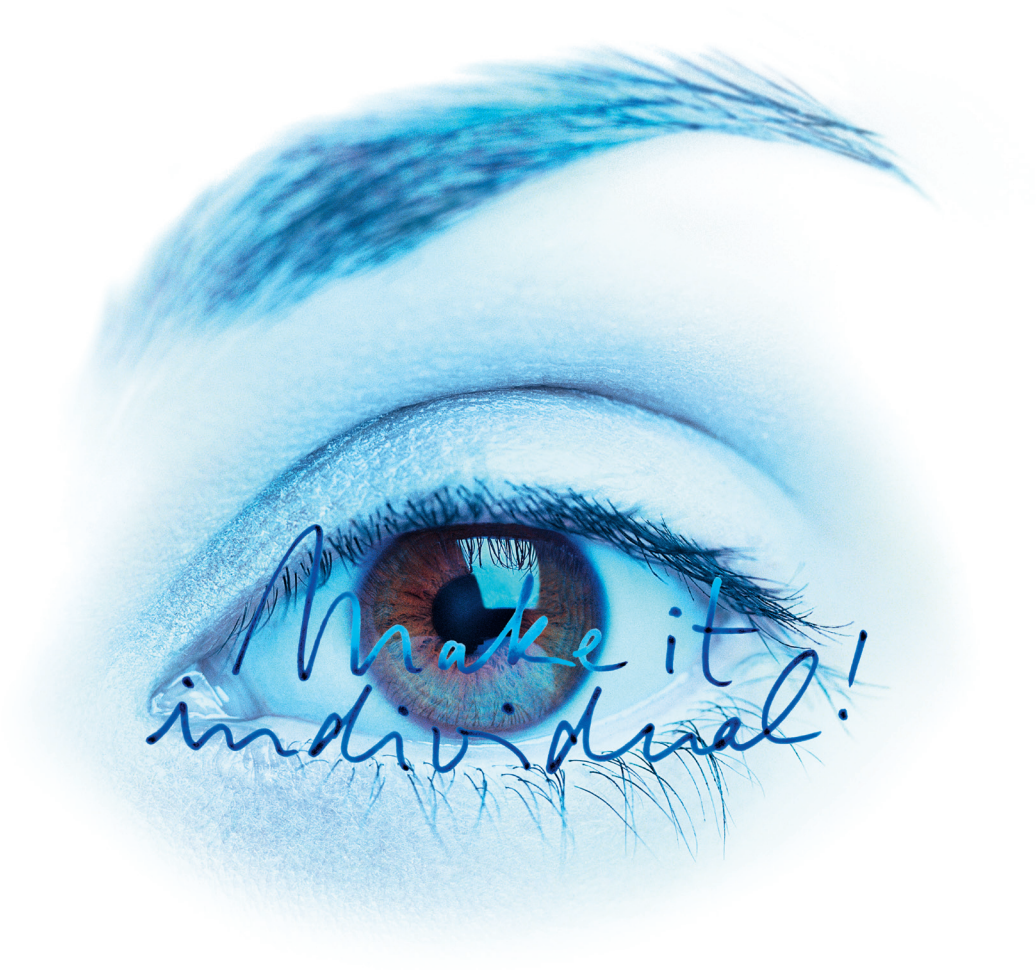
ICL™ / TORIC ICL™



Toric ICL™
High Definition Vision

STAAR Surgical AG
Hauptstrasse 104
P.O. Box 463
CH-2560 Nidau
Switzerland
Tel +41 32 332 88 88
Fax +41 32 332 88 99

info@staarag.ch

www.staar.com
www.iclinfo.info

STAAR SURGICAL
Vision of the future

INTRODUCTION

Welcome to a new era in refractive surgery. The ICL™ and Toric ICL™ are posterior chamber, sulcus located phakic intraocular lenses for the treatment of myopia, hyperopia and astigmatism. This manual will help guide you through the patient selection process, surgical procedure and follow-up care for your patients receiving the ICL™ and Toric ICL™. Welcome to the world of High Definition Vision.

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ICL™ / TORIC ICL™ USER'S MANUAL

ICL™ / Toric ICL™ Certification Process

ICL™ / TORIC ICL™ CERTIFICATION PROCESS

ICL™/ Toric ICL™ certification is a mandatory requirement for physicians who are interested in implanting the lens.

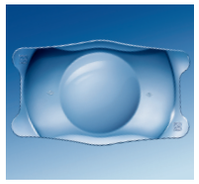
Physician certification for implantation of the ICL™ is part of STAAR Surgical's ongoing commitment to excellence in ophthalmology. A physician becomes eligible for certification after attending an official ICL™/ Toric ICL™ Certification Course.

Once eligible, the physician will complete certification by successfully selecting, implanting and managing his/her first surgical procedures with the support of an on-site STAAR Surgical ICL™/ Toric ICL™ Product Specialist.

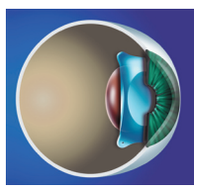
International certification courses are part of a two-step certification program. The first step in the process is a one-day course consisting of a four-hour didactic presentation, lens loading lab, live surgery observation and examination of post-operative patients. The second part of this program consists of successful completion of the first surgeries under the guidance of a Product Specialist.

The Product Specialist will contact the physician to arrange the logistics of the certification. Several important factors shall be discussed during this initial contact including:

- *Scheduling appropriate surgical and clinical staff trainings*
- *Scheduling pre-surgical time to review the surgical steps and lens-loading procedure*
- *Reviewing a pre-surgical checklist of the required instrumentation*
- *Reviewing potential ICL™/ Toric ICL™ candidates for accurate patient selection*



The Toric ICL™



The ICL™/ Toric ICL™ is a posterior chamber phakic IOL located in the sulcus

Please keep in mind when requesting a proctoring date that the certification usually takes up to three days:

- *Day one – train staff and review all necessary surgical steps*
- *Day two – perform surgery*
- *Day three – one-day postoperative patient review and answering any remaining questions*

Additionally, peripheral YAG Iridotomies must be performed one to two weeks prior to surgery. Also remember that careful selection of patients is critical to successful certification.

ICL™ / TORIC ICL™ USER'S MANUAL

Product Information

Indications for Use

Contraindications

Endothelial Cell Density

Lens Material

Optical Diameter

PRODUCT INFORMATION

Indications for Use

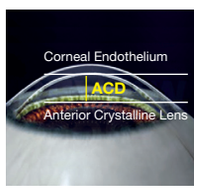
The ICL™ (myopic, hyperopic and toric version) is indicated:

- *For use in adults 21 to 45 years of age*
- *Available diopter range (0.5 D increments):*

ICM™ -3.0 D to -23.0 D
ICH™ +3.0 D to +21.0 D
Toric ICL™ -3.0 D to -23.0 D (sphere), +1.0 D to +6.0 D (cylinder)

- *With anterior chamber depth (ACD) of 2.8 mm or greater and a stable refractive history within 0.5 D for one year prior to implantation*
- *Intended for placement in the posterior chamber of the phakic eye*

Contraindications



The ICL™ is not recommended in patients:

- *Patients with unstable refraction in the past 12 months (myopia and / or astigmatism)*
- *Patients who do not fall in the range of pre-op myopia, hyperopia or astigmatism as outlined in the indications for use*
- *Patients under 21 or over 45 years of age*
- *Patients with an ACD of less than 2.8 mm as measured from the corneal endothelium*
- *Patients with low endothelial cell count, Fuchs' dystrophy or other corneal pathology*
- *Patients with a history of iritis, uveitis, synechiae, pigment dispersion syndrome, retinal disease (other than manifestation of myopic degeneration), chronic intraocular inflammation, macular degeneration, irregular astigmatism, keratoconus or cystoid macular edema in either eye.*
- *Patients with diabetic retinopathy in either eye*
- *Patients with glaucoma or diagnosis of ocular hypertension in either eye*
- *Patients with history of previous intraocular surgery (including refractive surgery) in the eye to be treated*
- *Patients who are amblyopic or blind in the fellow eye*
- *Patients with a progressive sight-threatening disease. Patients with retinal findings associated with pathological myopia are allowed.*
- *Patients with cataract in either eye or systemic collagen sensitivity*
- *Patients with insulin-dependent diabetes*
- *Patients who are pregnant or nursing*

Endothelial Cell Density

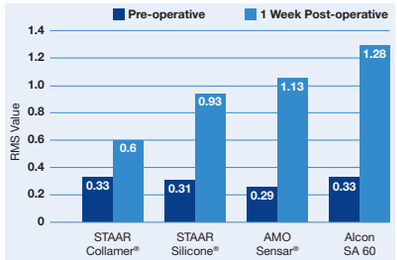
The following table indicates the minimum ECD per age group at time of implantation for three different ACD ranges and is to be used as a reference. This table was developed using rates of 2.47%, 2.44%, and 2.15% (the upper 90% confidence interval of the average cell loss for eyes with the specified ACD) for the ≥3.0 mm, ≥3.2 mm, and ≥3.5 mm groups, respectively. It sets minimum ECD criteria as functions of age that should result in at least 1000 cells/mm² at 75 years of age. The patient's ECD should be monitored periodically; methodology for determining cell density is at the discretion of the physician.

Age (years)	Minimum ECD ACD ≥ 3.0 mm	Minimum ECD ACD ≥ 3.2 mm	Minimum ECD ACD ≥ 3.5 mm
21 - 25	3875 cells/mm²	3800 cells/mm²	3250 cells/mm²
26 - 30	3425 cells/mm²	3375 cells/mm²	2900 cells/mm²
31 - 35	3025 cells/mm²	2975 cells/mm²	2625 cells/mm²
36 - 40	2675 cells/mm²	2625 cells/mm²	2350 cells/mm²
41 - 45	2350 cells/mm²	2325 cells/mm²	2100 cells/mm²
> 45	2075 cells/mm²	2050 cells/mm²	1900 cells/mm²

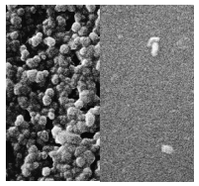
Lens Material

The ICL™ is lathe manufactured from a proprietary collagen copolymer material known as Collamer®. The material has a refractive index of 1.453 at 35ºC, a specific gravity of 1.21 and durometer hardness (shore A) of 45. The polymer material absorbs ultraviolet radiation, with light transmittance in the visible region of the spectrum of approximately 90% ±5% with over 90% of ultraviolet radiation blocked below 387 nm wavelength. Collamer® has several unique advantages. Since the collagen contained in the lens is negatively charged, it repels like charge particles such as proteins and cells. As such, the lens exhibits virtually no postoperative protein deposition.

Comparision of RMS values of different IOLs with a consistent pupil of 4.5 mm (Tracy VFA)



In vitro testing for protein adherence to acrylic and Collamer® materals.



Acrylic lenses: Cellular (protein) adherence.

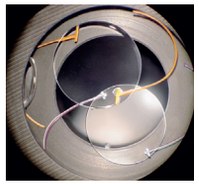
Collamer® lenses: Free of cellular or protein deposits.

Collamer® also exhibits an inherent anti-reflective coating property. The gradual change in refractive index at the surface of the lens results in a significant reduction in glare[1]. These properties combine to provide a lens material that induces fewer postoperative higher order aberrations than other lens materials[2]. The ICL™ provides exceptional quality of vision and biocompatibility for excellent long-term stability within the eye.

Optical Diameter

The optical diameter varies with the spherical power of the ICL™. The table below illustrates the relationship between optical diameter and power. Due to the magnification of the cornea, the effective corneal optical zone is greater than the actual optical diameter of the ICL™.

Collamer® (lens on the top) reduces lens surface glare compared to acrylic.



Power (D)	Optical Diameter (mm)	Effective Optical Diameter at Corneal Plane (mm)*
-3.0 to -12.0	5.50	7.30
-12.5 to -13.5	5.25	6.93
-14.0 to -16.5	5.00	6.62
-17.0 to -23.0	4.65	6.17

*Once implanted in the eye

1) Ossipov A. Comparison of internal reflectance patterns of Collamer®, acrylic and silicone. 1997.
2) Martin RG, Sanders DR. Higher order aberrations following implantation of four foldable lens designs, Presented at: ASCRS 2003.

ICL™ / TORIC ICL™ USER'S MANUAL

Pre-operative Preparation

Pre-operative Examination

Measuring White-to-White

Peripheral Iridotomy / Iridectomy (PI)

ICL™ / Toric ICL™ Power Calculation

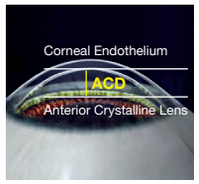
Lens Ordering

PRE-OPERATIVE PREPARATION

Pre-operative Examination

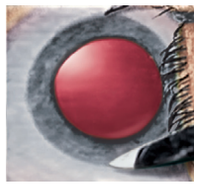
A typical comprehensive pre-operative eye examination should include the following:

- *Thorough ocular history*
- *Careful and precise manifest and cycloplegic refraction*
- *Visual acuity with and without correction*
- *Keratometry or corneal topography*
- *Corneal pachymetry*
- *Careful measurement of the ACD (as measured from the corneal endothelium to anterior surface of the crystalline lens)*
- *Pupil size in normal and scotopic conditions*
- *Endothelial cell count*
- *Intraocular pressure*
- *Comprehensive dilated slit-lamp exam to include the retina*
- *Careful measurement of the horizontal white-to-white distance*
- *Goniscopy*
- *Assessment of the crystalline lens*
- *Axial length (Biometry)*



Measuring White-to-White

There are various methods for measuring horizontal white-to-white distance. Accurate measurement of white-to-white is critical for proper sizing of the ICL™. To determine the ICL™ length, a nomogram using white-to-white and ACD is utilized. Physical measurement with calibrated calipers is one of the most reliable methods for obtaining the measurement. The patient should be reclined in the examination chair, the cornea anesthetized, and the measurement taken using magnification, such as surgical loupes or an operating microscope. This eliminates the potential parallax experienced at a slit lamp. Consider validating the measurement with a corneal topography unit. Evaluate any discrepancies between measuring devices. Sometimes a pterygium or other anomaly can cause a discrepancy, as can improperly calibrated calipers. It is essential that careful attention be taken when obtaining this critical measurement.



Peripheral Iridotomy / Iridectomy (PI)

One to two weeks prior to implantation of the ICL™, it is necessary to perform two peripheral laser Iridotomies. Peripheral Iridotomies are necessary due to the following reasons:

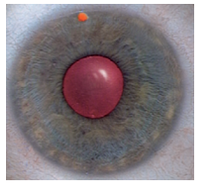
- *Upon constriction of the pupil, the ICL™ may block the passage of Aqueous from behind the lens to the anterior chamber, causing an acute pupillary block*
- *Incomplete removal of viscoelastic during surgery can cause a potential acute pressure rise*

Peripheral Iridotomies should be performed 1 to 2 weeks prior to surgery to allow the deposit and re-absorption of the pigment and the humoral factors of inflammation. The patency of the iridotomies should be confirmed prior to lens implantation. Experience from the US FDA clinical trial as well as international data suggests using a yttrium aluminum garnet (YAG) laser for the PIs. If the surgeon decides to move to the surgical PI technique, it is recommended that this is only done once the ICL™ surgical technique has been mastered. A two-step laser procedure, pre-treatment with an Argon Laser followed by Nd:Yag, is also a possibility. Two PIs should be placed superiorly, 90 degrees apart, in the mid-periphery. Each PI should be at least 1.0 mm in diameter. Some experienced surgeons choose to perform surgical Iridectomies although STAAR Surgical continues to recommend YAG PIs prior to ICL™ surgery, especially for the surgeon's first cases.

Tips for making PIs:

	YAG PI	Surgical PI by Scissors	Surgical PI by Vitrector
Size and number	Approximately 1 mm, 2 PIs required.	Require more experience to control. Usually range from 1 mm to 2 mm. Only 1 PI required. If too big, may interfere with vision.	Require more experience to control. Usually range from 1 mm to 2 mm. Only 1 PI required. If too big, may interfere with vision.
Location	Keep peripheral enough to avoid interference with vision, but not so peripheral that they do not function properly. PIs should be at least 90 degrees apart (approximately 10:30 and 1:30 o'clock).	Keep peripheral enough to avoid interference with vision, but not so peripheral that they do not function properly. Approximately 12 o'clock.	Keep peripheral enough to avoid interference with vision, but not so peripheral that they do not function properly. Approximately 12 o'clock.
Permeability	Ensure penetration of the pigment epithelium. Double-check full thickness permeability before surgery and re-YAG if needed.	Ensure penetration of the pigment epithelium. Ensure aspiration of pigment to avoid IOP spike after surgery.	Ensure penetration of the pigment epithelium. Ensure aspiration of pigment to avoid IOP spike after surgery.

Yag-PIs done prior to surgery at 10:30 and 1:30 o'clock



PI done with vitrector nearly at 12 o'clock. Main incision must be temporal

ICL™ / Toric ICL™ Power Calculations

Manifest or cycloplegic refraction is required to perform the lens power and length calculation.
Enter the following required data into the ICL™ / Toric ICL™ Power Calculation Software:

Sphere	**Manifest or cycloplegic**
Cylinder	**Manifest or cycloplegic**
Axis	**Valid range 0 to 180 degrees**
K Readings	**K1 and K2 values**
ACD	**Anterior Chamber Depth, valid range: 1 to 4.5 mm as measured from corneal endothelium to the crystalline lens. This value must be equal or greater than 2.8 mm**
WTW	**White-to-White, valid range 10 to 14 mm**
CT	**Corneal thickness in mm**
BVD	**Back Vertex Distance is set at a default of 12.0 mm, but should be changed if BVD used during refraction differs**

Lens Ordering

Send your calculation printout to your local STAAR Surgical representative.

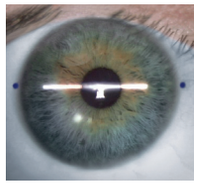
ICL™ / TORIC ICL™ USER'S MANUAL

Marking the Cornea for Toric ICL™ Implantation and Pupil Dilation

Marking the Cornea

Pupil Dilation

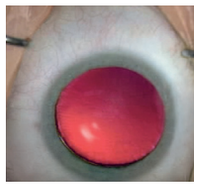
MARKING THE CORNEA FOR TORIC ICL™ IMPLANTATION AND PUPIL DILATION



The horizontal axis can be marked at the slit lamp

Marking the Cornea

- *Print out the implant diagram to know degree and direction of rotation of the Toric ICL™*
- *Prior to taking your patient to the surgery room, the cornea should be marked at the slit lamp*
- *Anesthetize the eye with topical anesthetic drops*
- *Using a cornea marker, mark the cornea at 0 and 180 degrees (slit lamp is useful for this)*
- *You can also use this horizontal mark as a guide to mark the eye at the degree to which the Toric ICL™ needs to be rotated. Some surgeons do this step once the patient is in the OR*



Adequate pupil dilation is crucial for ICL™ surgery

Dilation

A pupil size of 8.0 mm at the time of surgery is suggested.

- *Pupil dilation should be done prior to the patient entering the OR*
- *Instill 1 drop of flurbiprofen 1 hour prior to surgery to maintain pupil dilation*
- *Proper pupil dilation is usually achieved by instilling 1% tropicamide and 2.5% neosynephrine (or 10% if 2.5% is not commercially available) every 10 minutes for a minimum of 30 minutes and longer if necessary*
- *It is recommended to continue dilation drops until the patient enters the surgical suite*
- *If adequate dilation is not achieved or loss of dilation occurs, the addition of preservative-free intraocular epinephrine at a dosage of 0.1 ml of 1:10'000 solution may enhance dilation*
- **Adequate dilation is extremely important.** *Proceed with extreme caution if the pupil is <8 mm*

ICL™ / TORIC ICL™ USER'S MANUAL

ICL™ / Toric ICL™ Loading Technique

Required Instruments for Loading and Implantation

ICL™ / Toric ICL™ Handling Precautions

Step-by-Step Lens Loading

ICL™ / TORIC ICL™ LOADING TECHNIQUE

The procedure must be performed in a sterile environment under controlled conditions. The following loading and surgical technique guidelines are recommended by STAAR Surgical. These instructions are supplementary to the Directions For Use.

Required instruments for ICL™ loading and implantation

ICL™ front-loading forceps

Required Instruments for ICL™ Loading and Implantation

The following instruments are necessary for proper loading and injection of the ICL™:

- *Operating microscope*
- *Balanced Salt Solution (BSS)*
- *Methylcellulose-type viscoelastic*
- *ICL™ long-mouth forceps for placing lens into cartridge. Available from various suppliers*
- *ICL™ front-loading forceps for pulling the lens through the cartridge. Available from STAAR Surgical*
- *Cartridge (SFC45 FP) provided with the lens*
- *Foam Tip Plunger (FTP) provided with the lens*
- *MicroSTAAR injector MSI-PF (push action) or MSI-TF (twist action)*
- *Keratome blade for paracentesis*
- *Diamond or steel blade capable of 3.0-3.2 mm corneal incision*
- *ICL™ manipulator (available from several manufacturers)*
- *BSS on a canula for manual removal of viscoelastic*

ICL™ / Toric ICL™ Handling Precautions

- *Choice of the proper ICL™ / Toric ICL™ size should be carefully considered prior to surgery*
- *Check the label of the package for proper lens model and power*
- *Open the package to verify the labeled dioptric power of the lens*
- *Handle the lens by the haptic portion. Do not grasp the optic with forceps as this could potentially lead to damage to the smooth anterior and posterior optical surfaces*
- *Never touch the center of the optic with instruments once the lens is placed inside the eye. Inadvertent pressure through the optic could potentially damage the central crystalline lens, resulting in lens opacity*
- *STAAR Surgical recommends using only the MicroSTAAR® Injector System (Models MSI-TF and MSI-PF) to insert the ICL™ / Toric ICL™ in the folded state*
- *The ICL™ / Toric ICL™ should be carefully examined in the operating room prior to implantation*
- *The ICL™ / Toric ICL™ should not be exposed to any solutions other than the normally used intraocular irrigating solutions (eg, isotonic saline, BSS, viscoelastic)*
- *Keep the ICL™ / Toric ICL™ moist. It is recommended that the loaded ICL™ / Toric ICL™ be placed in sterile BSS prior to implantation to prevent dehydration*
- *The ICL™ / Toric ICL™ should be handled carefully. No attempt should be made to reshape or cut any portion of the lens. Do not apply undue pressure to the ICL™ / Toric ICL™ optical portion with a sharp object because this could perforate the optic*
- *The intended location of the ICL™ / Toric ICL™ is behind the iris within the posterior chamber and in front of the anterior capsule of the crystalline lens*
- *Hydroxypropylmethylcellulose (HPMC) viscoelastic is recommended for use with the ICL™*

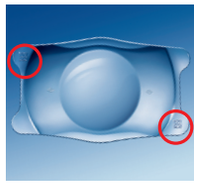
The long-term effects of phakic intraocular lens implantation have not been determined. Therefore, physicians should continue to monitor patients postoperatively on a regular basis.

Step-by-Step Lens Loading

Loading of the ICL™ is a critical component of the overall procedure and should be performed under the operating microscope prior to making any incisions. The delivery of the implant into the anterior chamber is largely dependent on the precise and careful loading of the ICL™.

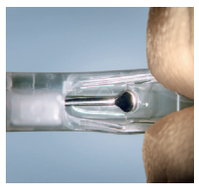
Steps to load the ICL™:

- *Open the pouch of the injector and place the sterile injector on a sterile field*
- *Open the foil pouch and the inner pouch containing the cartridge and place the* **inner sterile cartridge tray** *on a sterile field. Open the cartridge tray by «pulling up» where indicated*
- *Open the outer pouch of the Foam Tip Plunger (FTP) and transfer the* **inner sterile pouch** *to a sterile field. Open the inner pouch and remove the FTP and holder. The base of the FTP protrudes from the back of the holder*
- *Open the lens vial by lifting up the tab on top of the aluminum cap and pulling in a downward direction*
- *Place the FTP into the vial so that it will become well hydrated*



The markings on the footplates indicate the correct orientation of the ICL™ and the Toric ICL™ (picture shows Toric ICL™)

- *Fill the cartridge first with BSS followed by a partial fill with a methylcellulose-type viscoelastic, creating a trail out the back of the cartridge bay. This combination minimizes friction between the ICL™ and the cartridge walls*
- *Gently remove the ICL™ from the vial using the FTP and place the lens on the back portion of the cartridge. Place the FTP back into the vial for further hydration*
- *Grasp the ICL™ with the* **long-mouth forceps** *and inspect it under the operating microscope to identify and verify the correct orientation of the lens. The footplate marks on the leading right and trailing left haptic indicate that the correct (convex) side of the ICL™ is facing up. The other center marks are used to guide alignment during the loading of the lens into the injector cartridge and for axis orientation while implanting the Toric ICL™*



- *With the cartridge held in one hand and the forceps holding the ICL™ in the other, place the lens in the cartridge bay. Introduce the ICL™ into the cartridge bay so that the long axis of the lens is positioned under each siderail of the cartridge. This usually requires starting one long edge of the ICL™ under one rail and rolling the wrist to position the opposite side of the ICL™ under the opposing rail*
- *Close the jaws of the* **front-loading forceps** *and insert them into the barrel from the front of the cartridge. Advance the forceps through the cartridge until the jaws are about to contact the leading edge of the ICL™*
- *Open the jaws of the forceps and grasp the footplate of the ICL so that the lens positioning mark is aligned with the jaws*
- *Slowly pull the lens into the barrel while moving the cartridge in the opposite direction. Observe the lens positioning marks on either side of the ICL™ optic to confirm alignment as you advance the ICL™. Continue this process until the ICL™ is positioned within the cartridge so that its leading edge is within 2 mm of the end of the cartridge. Release the ICL™ and remove the forceps*

- *Any air bubbles should be evacuated from the loaded cartridge with methylcellulose-type viscoelastic injected into the tip of the cartridge using the cannula to backfill the cartridge*
- *Insert the FTP into the injector by placing the FTP back into its holder (foam side into the holder) and introducing the base of the FTP into the injector (the vertical tab of the holder is not intended to be snap-locked into the notch of the injector). While holding the tab in place, advance the injector plunger until the ball end of the FTP interlocks with the injector. A click can be felt and heard when the plunger is properly secured. Retract the injector plunger fully. The FTP will remain locked in place. Remove the holder by sliding it back out of the front of the injector*
- *Slide the fully loaded lens cartridge into the front of the injector and snap-lock the vertical tab into position*

- *Advance the plunger until it is in contact with the lens. The final lens position should be within approximately 1 mm of the end of the cartridge*
- *Inspect the lens orientation under the operating microscope. The clear funnel of the cartridge enables identification of the center marks on each side of the optic. These marks should be visible at the 12 o'clock position and be in straight alignment down the shaft. If there is misalignment or improper orientation, the ICL may be twisted and should be injected into the cartridge tray and the loading process repeated*
- *The fully assembled injector is placed tip down into a container of BSS to maintain lens hydration. The maximum recommended time for the loaded ICL™ to remain in the injector prior to surgery is 1-2 minutes*

- *Note that there are two types of injectors available, a twist type (MSI-TF) and plunger type (MSI-PF). The twist type offers a more controlled injection but requires a two-handed technique. The plunger style injector can be operated with only one hand and the fellow hand can be used to stabilize the globe. Either injector can produce the desired outcome and is a matter of surgeon preference*

ICL™ / TORIC ICL™ USER'S MANUAL

Surgical Procedure

Patient Preparation

Anesthesia

Surgical Technique

SURGICAL PROCEDURE

Patient Preparation

ICL™ surgery should be performed in a sterile surgical environment under controlled conditions. A sterile field should be created by using a standard preparation and drape appropriate for intraocular surgery.

Anesthesia

Topical anesthesia is typically used. The use of intracameral lidocaine is controversial (intracameral lidocaine has been associated with partial loss of mydriasis, which is contraindicated for the procedure). Peribulbar, retrobulbar, and/or general anesthesia may also be used. If using retrobulbar anesthesia, please remember that the forward pressure associated with retrobulbar anesthesia may decrease the ACD, resulting in difficulty and sometimes inability to insert the ICL™.
Topical anesthesia may be obtained with the following topical agents just prior to surgery:

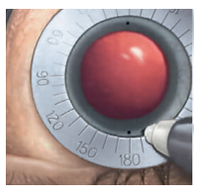
- *0.75% bupivicaine*
- *0.5% tetracaine*
- *2.0% lidocaine*

Preoperative sedation is suggested. Intravenous access should be established with sedation appropriate for patient comfort. The intended level of sedation results in a conscious, cooperative, and comfortable patient. Light induced sleep with the accompanying risk of uncontrolled awakening should be avoided. Oral sedatives may also be useful, but may not be as predictable as intravenous sedatives.

Surgical Technique

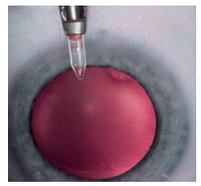
The ICL™ surgical technique contains many elements familiar to cataract surgeons. The steps described below require exact execution to achieve optimal outcomes.

Marking of the Cornea for Toric ICL™ Alignment
If the target axis was not marked at the slit lamp, the pre-op corneal marking of the horizontal axis should be used as a reference to mark the exact axis to which the Toric ICL™ will be aligned according to the Toric ICL™ Orientation Diagram.

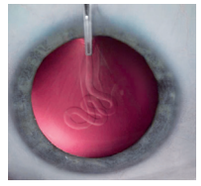


Intraoperative marking of the exact alignment axis for the Toric ICL™

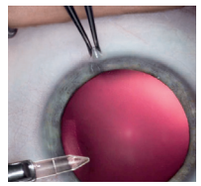
Paracentesis
Employing a temporal approach, two 1-mm paracentesis incisions are fashioned at 12 o'clock and 6 o'clock. Stay shallow and do not penetrate too far. Avoid inadvertent touch or perforation of the anterior lens capsule. Two paracenteses are recommended for ICL™ manipulation. It is difficult to make the paracentesis once the main incision has been made due to the eye becoming soft.



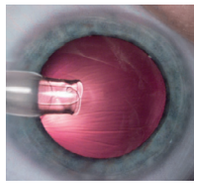
Injection of Viscoelastic
An HPMC-type viscoelastic is preferred due to its ease of removal and the low resistance offered to the unfolding of the ICL™. Published reports indicate that hyaluronic-acid-type viscoelastics may interfere with fibroblast proliferation of the anterior capsule and could cause long-term effects not yet known[1]. Additionally, the use of higher molecular weight viscoelastic agents can cause prolonged unfolding time that may prevent the lens from unfolding, requiring removal and replacement, or may interfere with the positioning of the implant. The viscoelastic cannula tip should not extend more than 1 mm beyond the wound. The viscoelastic is injected until the eye is moderately firm; however, do not overfill the chamber. It should be possible to view the viscoelastic chains throughout the fill. It is important to insert the cannula past the inner corneal wound margin to avoid visco-dissection of Descemet's membrane and endothelial detachment. It is advisable to avoid injecting viscoelastic posterior to the ICL™ because there is no access to aspirate or irrigate this area once the ICL™ has been positioned.



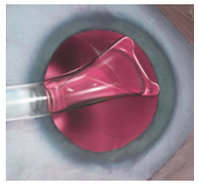
Clear Corneal Temporal Incision
The temporal approach provides ideal exposure for a level working plane and avoids a posterior-angled entry. The clear-corneal incision should have a chord length of 3.0 to 3.2 mm with a 2.0 mm tunnel and be made on a parallel plane to the iris. This approach avoids touching of the crystalline lens or the corneal endothelium and provides adequate room for the lens injector and a secure self-sealing closure. Additional viscoelastic may be injected after completion of the incision to maintain the deep architecture of the anterior chamber. Once again, do not overfill the chamber.



1) Ossipov A. Comparison of internal reflectance patterns of Collamer®, acrylic and silicone. 1997.



ICL™ / Toric ICL™ Injection
The loaded ICL™ is brought into the surgical field and the tip of the cartridge is inserted into the clear corneal wound. The tip of the cartridge should extend just beyond Descemet's membrane.



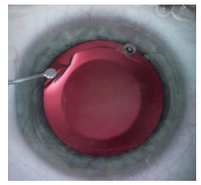
Once the tip is in proper position (bevel down) and the injector is stabilized, the ICL™ should be slowly injected into the anterior chamber using an advance-and-pause technique. This technique, sometimes referred to as a «tapping» motion, allows the ICL™ to gradually exit the tip of the injector and unfold in a slow and controlled manner.

To avoid inadvertent touch of the crystalline lens, do not attempt to direct the leading footplates of the ICL™ under the iris. As the ICL™ unfolds, it is necessary to visualize the leading right footplate mark to ensure proper orientation of the ICL™. If you do not visualize the footplate landmark, STOP and rotate the cartridge until proper orientation is achieved, then continue injecting. If the landmark is still not visualized, STOP. Remove the ICL™ along with the cartridge, reload, and start the injection again. Remember, as long as the ICL™ remains in the cartridge, you still have control of the implantation process.

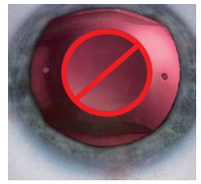
When one half to three fourths of the ICL™ has exited the injector, a slow unfolding of the ICL™ will occur. If the ICL™ has not started to unfold at this point, pause and allow the leading footplates to unfold before injecting the remaining portion of the implant. If the ICL™ is injected completely into the anterior chamber before the front footplates unfold, the lens can present upside down, which will require removal, inspection, and reinsertion. The unfolding of the ICL™ should be symmetrical along the long axis of the implant.

To ensure the anterior-posterior orientation of the ICL™ within the anterior chamber, any spiraling of the implant as it leaves the cartridge must be neutralized by counterrotation of the injector by the surgeon.

Positioning the ICL™
Once the ICL™ is situated in the anterior chamber, additional viscoelastic is injected over the ICL™ to deepen the chamber and direct the implant posteriorly. Inject viscoelastic until the iris-lens diaphragm shifts backward. The ICL™ must now be repositioned posterior to the iris plane. The paracentesis incisions are used to provide access for the ICL™ manipulation instrument. The distal or nasal footplates should be positioned first. If any difficulty with pupil size or positioning occurs, this will leave the footplates closest to the temporal incision available for easier removal of the ICL™.

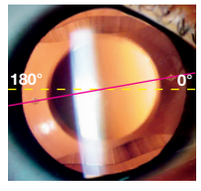


When working inside the eye, the optical zone of the ICL™ should be considered the «no touch zone». *All instruments within the anterior chamber should be kept to the peripheral area outside of the optical zone of the ICL™. With the ICL™ manipulator in contact with the peripheral part of the footplate, the proper motion is gentle posterior pressure combined with a slight rotation of the instrument with the fingers at one clock-hour or less. Once the first footplate is under the iris, the maneuver is repeated with each of the remaining footplates until all are posterior to the iris plane. Rotation of the ICL™ is to be avoided once the ICL™ is positioned behind the iris. Once positioned behind the iris, subtle adjustments are achieved by manipulation on the lens body between the footplate and optic. Never depress the optic itself.*



The central optic of the ICL™ is considered a «no-touch zone»

Aligning the Toric ICL™
Position the Toric ICL™ at the proper axis according to the diagram / corneal markings (maximum rotation 22 degrees). Always manipulate on the haptic or 'body' of the lens, never on the optical zone.



The Toric ICL™ is custom-made to the patient's refraction and needs to be rotated according to the diagram provided by the software at maximum 22 degrees

Removal of Viscoelastic
Irrigating the anterior chamber with BSS on a 27-gauge cannula with slight incisional pressure is generally sufficient to flush methylcellulose from the eye. Bimanual irrigation and aspiration is also effective; however, standard automated irrigation and aspiration risk dislocating the ICL™ and should be avoided. Iris prolapse and trampolining of the implant may also occur with standard automated irrigation. Once the viscoelastic has been removed, Toric ICL™ alignment must be reconfirmed.

Constricting the Pupil
Once the footplates are visually confirmed to be posterior to the iris, the lens is positioned properly and all of the viscoelastic has been removed, the pupil is pharmacologically constricted with Miochol®. Miochol® is preferred to Miostat® due to the lower risk of ciliary spasm, which can cause pain and prolong visual recovery due to induced myopia. Once the viscoelastic is removed and the pupil has constricted, some surgeons inject intracameral antibiotics. At this point PIs should be checked for patency. The wound should then be tested to confirm a self-sealing closure.

Post-operative Medication
STAAR Surgical recognizes a typical postoperative regime may include topical antibiotic and application of anti-inflammatory medications following surgery. Some surgeons will also use a steroid drop. The patient should continue the medications using the standard post-operative regime. Typically, antibiotic 4 times a day for 1 week, the anti-inflammatory three to four times a day on the first post-operative day and, if used, the steroid drops four times a day, tapering off over a two- to three-week schedule.

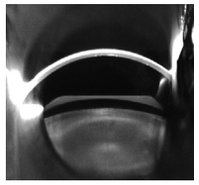
ICL™ / TORIC ICL™ USER'S MANUAL

Postoperative Assessment and Complication Management
Early Postoperative Examination (2-4 hours)
Evaluating the Vault
Routine Postoperative Examination
Considerations
Power / Size
Wound Construction
Improper Loading
Poor Insertion
Early Postoperative Complications
IOP Spike / Elevated IOP
Inadequate Vault
Excessive Vault
Traumatic Cataract
Late Postoperative Complications
Cataract
Decentered ICL™
Atypical Late Postoperative Findings
Pigment on the ICL™
Iris Transillumination
Technique for ICL™ / Toric ICL™ Removal

POST-OPERATIVE ASSESSMENT AND COMPLICATION MANAGEMENT

Early Postoperative Exam (2-4 Hours)

- *IOP*
  - *IOP is checked in this early post-operative exam because PIs may not be patent, viscoelastic may be trapped in the PIs or viscoelastic may be retained in the Aqueous*
- *Slit lamp examination to assess:*
  - *Wound sealing*
  - *Centration of the implant*
  - *Inflammation*
  - *Vault of the ICL™*
  - *Anterior chamber configuration*

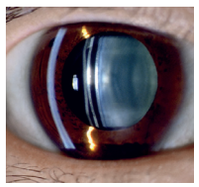


Once in the eye, an appropriately sized ICL™ provides safe distance from the endothelium and the crystalline lens

Evaluating the Vault

The vault is the distance from the posterior surface of the ICL™ to the anterior surface of the crystalline lens. The generally accepted range of vault of an ICL™ once implanted is 0.5 to 1.5 corneal thickness. This subjective measurement may be estimated at the slit lamp by visually comparing the relative corneal thickness to the space observed between the anterior surface of the crystalline lens to the posterior surface of the ICL™.

The vault is best viewed using a thin optic section with an optic / light source angle of 30 to 45 degrees. The focus is alternated posterior to the vault area and anterior to the corneal thickness to complete the comparison and measurement. The vault may also be objectively measured using a variety of available instruments.



The ICL™ vault is ideal if between 0.5 to 1.5 corneal thickness

Routine Postoperative Examination

An uncomplicated case will generally follow a 1-day, 1-week, 1-month, and 1-year postoperative evaluation schedule. Appropriate testing includes:

- *Distance and / or near visual acuity*
- *Refraction*
- *Slit lamp exam to evaluate:*
  - *Position / centration of implant*
  - *Vaulting of implant*
  - *Anterior chamber configuration*
  - *Anterior chamber inflammation*
  - *Evaluation of crystalline lens*
- *IOP*
- *Endothelial cell count (may be done at the one year exam. Some surgeons include a fundus and retinal exam as part of routine annual care)*

Considerations

- Power and Size

It is critical that care be taken in the subjective measurements required for proper power and sizing of the ICL™. As with corneal refractive surgery, a skilled technician should be performing the routine refractions and measurements.

When measuring white-to-white, it is important to compare physical measurements (caliper as described in previous sections) with topographical measurements and investigate large discrepancies. Additionally, it is critical to calibrate the caliper to ensure accurate measurement.

- Wound Construction

Proper wound construction is critical to successful implantation and postoperative recovery. The angle of the incision should be parallel to the iris plane. If the incision is angled posteriorly, inadvertent touching and / or penetration of the crystalline lens during wound construction may occur. If this occurs, cancel the ICL™ surgery and perform clear-lens extraction with IOL implantation.

Proper sealing of the wound is also critical to avoid postoperative intraocular infection. If the wound is not properly constructed, iris prolapse is more likely.

- Improper Loading

ICL™s that are not loaded properly may be twisted in the cartridge. During injection into the chamber, the implant may exit in an uncontrolled manner and may tear or be inverted with the convex side down. Either of these flawed loadings and injections may require ICL™ removal and re-insertion in the prescribed manner.

- Poor Insertion

Insertion of the ICL™ can produce complications in several instances:

- *Insertions that proceed too quickly and do not allow the leading footplates to unfold may cause the implant to be inverted with the convex side down*
  - To prevent this complication, pause during the insertion when the ICL is 50% to 75% out of the tip, until the front footplates open and the correct orientation is verified
- *The ICL™ may open or unfold in an unsymmetrical manner with one footplate opening earlier, which causes the implant to begin a turn in one direction. If continued and not corrected, the ICL™ may invert*
  - To correct this insertion, you can rotate the injector to a position where the implant will have the leading footplates in proper position

Early Postoperative Complications

- IOP Spike / Elevated IOP

IOP elevation should be treated medically. Diagnosis of the cause of the IOP elevation should guide the user in the proper management. Please see the «Decision Tree» at the end of this manual. Topical and / or oral IOP-lowering agents may be considered. The most common factors contributing to IOP elevation after ICL™ implantation include the following:

- *Retained viscoelastic in the anterior chamber (most common)*
- *Non-permeable PIs*
- *Blocked PIs*
- *Undersized PIs*
- *Oversized ICL™ (least common)*

If large amounts of viscoelastic are left in the eye, burping of the main incision may help, as well as further irrigation and aspiration.
If PIs are not functioning properly, revision of these openings using the YAG laser will allow pressure to return to normal levels and avoid pupillary block and associated complications.
If the lens inserted is longer than required for the anatomy of the eye, overvaulting of the lens may occur, with or without increased IOP (refer to the «Excessive Vault» section below).

- Inadequate Vault

The appearance of a low vault within the first post-operative hours is not unusual. The vault may increase within the next post-operative days and this should be confirmed at a later stage. Late or early inadequate vault alone is not a complication. The decision whether or not to remove or exchange for a longer lens should be based on individual surgeon experience although STAAR Surgical does not recommend removing or exchanging the lens unless progression or clinically significant loss of BSCVA has been diagnosed.

- Excessive Vault

If the lens inserted is longer than required for the anatomy of the eye, overvaulting of the lens may occur. It is recommended to leave this lens in place unless the patient is symptomatic or if the vault is excessive enough to potentially compromise the angle or the patient's vision. If the patient exhibits elevated IOP with anterior displacement of the iris, narrowing of the angle and shallowing of the anterior chamber, in the presence of fully working Iridectomies (i.e. once pupillary block due to non fully functioning PIs and / or remaining visco has been ruled out), removal of the ICL™ and replacement with a shorter length lens is recommended.

Experience from international surgeons advocates dilation of the patient if an early post-operative IOP spike occurs in the presence of high vault. This will assist in the differential diagnosis between true pupillary block due to non-working PIs / remaining visco versus true oversized ICL™.[3]

- Traumatic Cataract

In case of significant intraoperative trauma to the crystalline lens, the patient should be evaluated and clinical data obtained for IOL calculation. Penetration of the anterior capsule is rare, however, should this occur, the surgeon should convert to clear-lens extraction with IOL implantation. Anterior capsular «touch» may occur while tucking the footplates of the implant. If the rule of «no crossing of the optic» is observed, these small opacities should be peripheral in location and not visually significant.

3) Please refer to the «Decision Tree» on page 40

Late Post-operative Complications

- Cataract

A shallow vault, one-fourth of the corneal thickness (~150 microns) or less, should be monitored closely for development of anterior capsular haze. Shallow vault may be one contributing factor for the development of late anterior subcapsular opacity. In the absence of opacities and / or loss of visual acuity, shallow vault alone does not necessarily necessitate ICL™ exchange.
Shallow vault should be monitored periodically. STAAR Surgical recommends leaving the lens implanted unless progression of the opacity and / or loss of BSCVA has been diagnosed.

- Decentered ICL™

Decentration of the ICL™ has been extremely rare. Should a decentered ICL™ occur, an evaluation of the angle to confirm the posterior positioning of all footplates should be done. If the ICL™ requires repositioning, care should be taken to avoid contact with the anterior surface of the crystalline lens. The repositioning should take place in a surgical environment using an operating microscope.

Atypical Late Post-operative Findings

- Pigment on the ICL™

With the Iridotomy creation one or two weeks prior to surgery, pigment movement in the anterior chamber is likely to happen. In most cases, it is self-limiting and rarely reaches a level of clinical significance. One may observe pigment on the anterior surface (thickest peripheral portions of the myopic optics) and more often on the posterior surface. If pigment dispersion is significant, the eye should be evaluated for signs of secondary glaucoma. In rare cases of continuing pigmentary dispersion with subsequent IOP increase, the ICL™ may need to be removed.

- Iris Transillumination

Inadequate position of the ICL™ footplate may be correlated to iris transillumination defect. Careful placement technique combined with correct sizing of the ICL™ should minimize this occurrence.

Technique for ICL™ / Toric ICL™ Removal

The ICL™ may be removed, if indicated, in a controlled and atraumatic manner.

- *The eye is dilated using the same medications and timing as in the original surgery:*
  - Drops instilled a minimum of 3 times with the following topical medications at 10-minute intervals until an 8mm pupil is achieved:
  - 1 % tropicamide
  - 2.5 % neosynephrine
- *The original paracentesis and incision may be used to access the anterior chamber*
- *The ICL™ is elevated by use of an HPMC-type viscoelastic on a standard cannula directed through the paracentesis incision at the central edge of the implant. A slow, controlled application of viscoelastic will flow beneath the ICL™ and increase the vault, which may ease the removal*
- *Through the main incision, the ICL™ manipulator is used with a reverse technique to bring the proximal footplate into the anterior chamber above the iris*
- *The tucker is placed beneath the ICL™ between the footplate and optic and the implant footplate is pulled to the incision site*
- *Once a footplate is pulled though the incision and exposed, the front loading forceps can grasp this area and move the implant out through the incision*

DECISION TREE

Early post-op exam (3-6 hours after surgery)
shows high IOP (>30-40 mmHg) & high vault (>1.5 corneal thickness)

COMPARATIVE STUDIES OF ICL™ AND TORIC ICL™

Table 1: Characteristics of the currently available Myopic (V4), Hyperopic (V3) and Toric ICL™ (V4) models

ICL™	Spherical Power	Cylindrical Power	Optical Diameter	Optic/Haptic Thickness	Overall Height
Myopic	-3.0 to -12.0 D	0.0	5.50 mm	0.3 to 0.5 mm	1.15 to 1.77 mm
model (V4)	-12.5 to -13.5 D	0.0	5.25 mm	0.5 mm	1.08 to 1.78 mm
	-14.0 to -16.5 D	0.0	5.00 mm	0.5 to 0.6 mm	1.12 to 1.89 mm
	-17.0 to -23.0 D	0.0	4.65 mm	0.5 to 0.7 mm	1.19 to 2.05 mm
Hyperopic	+3.0 to +12.0 D	0.0	5.50 mm	0.2 mm	1.25 to 2.29 mm
model (V3)	+12.5 to +13.5 D	0.0	5.50 mm	0.2 mm	1.61 to 2.36 mm
	+14.0 to +16.5 D	0.0	5.50 mm	0.2 mm	1.68 to 2.49 mm
	+17.0 to +21.5 D	0.0	5.50 mm	0.2 mm	1.82 to 2.79 mm
Toric model	-3.0 to -12.0 D	+1.0 to +6.0 D	5.50 mm	0.3 to 0.5 mm	1.5 mm
(V4)	-12.5 to -13.5 D	+1.0 to +6.0 D	5.25 mm	0.5 mm	1.5 mm
	-14.0 to -16.5 D	+1.0 to +6.0 D	5.0 0mm	0.5 to 0.6 mm	1.5 to 1.6 mm
	-17.0 to -23.0 D	+1.0 to +6.0 D	4.65 mm	0.5 to 0.7 mm	1.6 to 1.7 mm

Table 2: Comparative studies of ICL™ and Toric ICL™ for myopia and compound myopic astigmatis

	El-Danasoury et al‡	El-Danasoury et al‡	El-Danasoury et al‡	Sanders et al	FDA clinical trial	Uusitalo et al	Pienda-Fernandez et al	Zaldivar et al
Dates of surgery	**2005 - 2006**	**2005 - 2006**	**2005 - 2006**	**2002 - 2003**	**1998 - 2001**	**1998 - 2000**	**1998**	**1993 - 1996**
ICL Model	**V4**	**V4**	**V4 (toric)**	**V4 (toric)**	**V4**	**N/A**	**V3, V4**	**2020, V1, V2, V3**
Population								
Mean age (years)	27	29.5	26	36.4	36.5	39	34.5	34
Eyes operated (eyes)	42	35	68	210	523	38	18	124
Eyes reported (eyes)	34	29	58	186	428	36	18	124
Percent of eyes reported (%)	81	82.9	85.3	88.6	81.8	94.1	100	100
Mean follow up (months)	12	12	12	12	12	13	26.6	11
Pre-operative Refraction								
Mean MRSE (D)	-10.50 ± 2.19	-4.69 ± 1.59	-7.07 ± 3.35	-9.36 ± 2.66	-10.05 ± 3.75	-15.1	-15.27 ± 3.47	-13.38 ± 2.23
Range MRSE (D)	-17.25 to -8.38	-8.00 to -2.13	-13.38 to -2.25	-19.50 to -2.38	-20.00 to -3.00	-29.00 to -7.75	-21.25 to -2.75	-18.63 to -8.50
Mean refractive Cylinder (D)	0.73 ± 0.29	0.42 ± 2.6	2.34 ± 0.81	1.93 ± 0.84	N/A	N/A	1.8 ± 1.30	2.13 ± 1.51
Range refractive cylinder (D)	0.00 to 1.00	0.00 to 1.00	1.25 to 4.75	1.25 to 475	N/A	N/A	0.50 to 4.00	0.00 to 6.00
Post-operative MRSE								
Mean MRSE (D)	-0.07 ± 0.34	-0.14 ± 0.27	-0.16 ± 0.41	0.05 ± 0.46	-0.50 ± 0.98	-2.00 ± 2.48	-0.62 ±0.81	-0.78 ± 0.87
Range MRSE (D)	-0.63 to 0.38	-0.75 to 0.25	-1.75 to 1.13	-2.25 to 1.00	-8.00 to 1.13*	-13.00 to 0.13**	-2.75 to 0.75	-3.50 to 1.63
Percent within 0.50 D (%)	79	86.2	84.5	76.9	61.6	71.1	22.2	44
Percent within 1.00 D (%)	97	100	93.1	97.3	84.7	81.6	61.1	69
Percent within 2.00 D (%)	100	100	100	100	96.7	N/A	N/A	N/A
Post-operative Cylinder								
Mean (D)	0.65 ± 0.43	0.43 ± 0.28	0.38 ± 0.66	0.51 ± 0.48	N/A	N/A	N/A	0.96 ± 0.85
Range (D)	0.00 to 1.25	0.0 to 1.25	0.00 to 1.75	0.00 to 3.00	N/A	N/A	N/A	0.00 to 3.75
Baseline SCVA								
20/16 or better (%)	4.8	10.3	6.9	4.8	N/A	N/A	N/A	N/A
20/20 or better (%)	73.8	82.8	46.6	83.1	67.7	23.9	N/A	5
20/40 or better (%)	97.6	100	96	NA	96.9	63.2	N/A	80
Post-operative UCVA								
20/16 or better (%)	11.8	13.8	12.1	N/A	N/A	N/A	N/A	N/A
20/20 or better (%)	85.3	86	67.2	83.1	60.1	5.3	5.5	2
20/40 or better (%)	100	100	100	N/A	92.5	52.6	44.4	68
Post-operative SCVA								
20/16 or better (%)	14.4	20	17	37.6	N/A	N/A	N/A	N/A
20/20 or better (%)	94	96	88	96.8	82.4	39.5	N/A	19
20/40 or better (%)	100	100	100	N/A	98.1	94.7	N/A	93
Change in BSCVA								
Loss ≥ 2 or more lines	0	0	0	1.6	0.7	N/A	5.6	0.81
Loss 1 line (%)	8.8	6.9	1.7	7.5	5.4	6.2	N/A	N/A
Unchanged (%)	26.5	48.3	36.1	14.5	44.3	N/A	N/A	N/A
Gain 1 line (%)	47.1	34.5	43.1	57.5	40	31.3	38.8	N/A
Gain ≥ 2 or more lines (%)	17.6	10.3	19	18.9	9.6	40.6	N/A	36
Complications								
Visually insignificant lens opacities (%)	2.9	0	1.7	2.4	2.1	2.6	5.6	2.42
Visually significant cataract (%)	2.9	0	0	0.5	0.4	2.6	5.6	0
Pupillary block (%)	0	0	0			7.9***	12.5***	4.8
Percent of secondary interventions (total)	**2.9**	**0**	**5.3**	**2.4**	**2.3**	**13.2**	**16.7**	
Removal (%)	0	0	0	1.6	0	2	0	3.3
Replacement (%)	0	0	0	0.5	1.7	0	0	1.6
Repositioning (%)	0	3.4	0	0	0.7	0	0	0.8
Axis realignment (%)	0	0	5.3	0.5	0	0	0	0
Removal with Cataract extraction (%)	2.9	0	0	0	0.4	5.3	5.6	0
Laser Iridotomies enlargement (%)	0	0	0	0	0	7.9	11.1	0

‡Ongoing studies
9.9 % eyes were not corrected to emmetropia **31.6 % eyes were not corrected to emmetropia * All eyes that developed pupillary block had laser iridotomies before ICL™ implantation*

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USER'S MANUAL

CHAPTER ONE

CHAPTER TWO

CHAPTER THREE

CHAPTER FOUR

CHAPTER FIVE

CHAPTER SIX

CHAPTER SEVEN